REMARKS

Claims 1 and 4-22 are pending in the subject application. Claim 1 has been amended to more particularly define the filtering step (b) of the claimed method as involving binding the filtered nucleic acid directly to the porous matrix. This amendment is supported by the specification, *e.g.*, page 2, second paragraph and by the language of original claim 1. The amendment is made merely to make this distinction clear. Accordingly, no new matter is added by this amendment.

It is respectfully submitted that the amendment places the claims in condition for allowance.

I. Rejection of Claims 1, 5-10, 14 and 16-18 Under 35 U.S.C. § 102(b) Over Smith et al.

Claims 1, 5-10, 14 and 16-28 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Smith et al. The Examiner asserts that Smith teaches all of the elements of the claimed process, including binding of nucleic acids to a silica based or coated porous matrix. Applicants respectfully disagree.

The amendment to claim 1 above clarifies that the nucleic acid that is filtered through the porous matrix used in the present invention is directly bound to the matrix. In contrast, Smith teaches use of an ion exchange matrix attached to a porous matrix support, whereby the nucleic acid attaches to the ion exchange matrix, not the porous matrix support. Thus, Smith does not teach or suggest the claimed invention.

Accordingly, the rejection of claims 1, 5-10, 14 and 16-18 under 35 U.S.C. § 102(b) as allegedly being anticipated by Smith et al. is respectfully traversed.

II. Rejection of Claim 4 and 19-22 Under 35 U.S.C. § 103(a) Over Smith et al. and Colpan

Claims 4 and 19-22 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Smith et al. in view of Colpan. The Examiner applies Smith as above and relies on Colpan as teaching a method for rapid isolation of genomic DNA having a size in the range of from 1 to 50kb using multiple layers of membranes having different pore sizes. The Examiner concludes therefore, that it would have been obvious to one of ordinary skill in the art to have used the filter matrices of Smith in the arrangement of Colpan.

Applicants respectfully disagree.

As discussed above, the present invention is based in part on the binding of nucleic acids directly to the silica based or coated porous matrix used in the claimed filtering process, whereas Smith et al. bind nucleic acids to a pH dependent ion exchange matrix which is bound to a solid support. Smith et al. does not teach binding of nucleic acids directly to a silica based or coated support and thus, even if one of skill in the art were to use the arrangement suggested by Colpan, the result would not be the present invention.

Colpan merely teaches certain of the structural features used in the present invention for the isolation of plasmid and genomic DNA. However, in each instance where genomic DNA is isolated, Colpan teaches that the cells are lysed in the presence of guanidinium (See Examples 10 and 11).

The combination of Colpan and Smith et al. fails to disclose or suggest the present invention. First, Smith et al. teaches the use of an ion exchange matrix for binding the nucleic acids after disrupting the cells and does not disclose or suggest binding directly to the porous silica based or coated matrix. Second, Colpan teaches use of guanidine-HCl in each instance where genomic DNA is the target of the isolation procedure. Thus, even if one were to combine

the two cited references in the manner suggested by the Examiner, the result would not be the present invention where genomic DNA is released from cells in the absence of a chaotropic agent and captured by direct binding to a silica based or coated porous matrix.

Accordingly, the rejection of claims 4 and 9-22 under 35 U.S.C. § 103(a) over Smith et al. in combination with Colpan is respectfully traversed.

III. Rejection of Claims 11-13 Under 35 U.S.C. § 103(a) Over Smith et al.

Claims 11-13 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Smith et al. The Examiner asserts that it would have been obvious to use filters with different pore sizes in Smith's filters to enable capture of genomic DNA. The Examiner concludes, therefore, that the claimed invention would have been obvious to one of skill in the art.

Applicants respectfully disagree.

As discussed above, Smith et al. does not disclose a filter system that binds DNA directly. Instead, Smith utilizes an ion exchange ligand attached to a solid support such as a silica bead. There is no teaching or suggestion that direct binding to the porous matrix can replace use of ion exchange resins. Thus, regardless of the size of the pores in the solid matrix, the invention of Smith et al. does not render the claimed invention obvious.

Accordingly, the rejection of claims 11-13 under 35 U.S.C. § 103(a) over Smith et al. is respectfully traversed.

IV. Rejection of Claim 15 Under 35 U.S.C. § 103(a) Over Smith et al. and Heid et al.

Claim 15 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Smith et al. in view of Heid et al. Smith et al. is applied as above and as teaching amplification of isolated DNA; Heid is relied on as teaching quantitative real-time PCR on

human genomic DNA. The Examiner concludes, therefore, that it would have been *prima facie* obvious to one of ordinary skill in the art to have applied real-time PCR to analyze the genomic DNA isolated by the method of Smith et al.

Applicants respectfully disagree.

The present invention differs from and is not rendered obvious by the teachings of Smith et al., alone or in combination with Heid et al. As discussed above, Smith et al. teaches use of a solid support porous matrix to which are attached pH dependent ion exchanges matrixes which bind nucleic acids from a cell lysate. The nucleic acid is not bound directly to the porous matrix as in the present invention. Heid et al. does not cure this deficiency in the primary reference.

Heid et al. merely teaches a method of carrying out quantitative real-time PCR. This reference is silent as to how the DNA used in the PCR assay is isolated. As such, the combination of cited prior art fails to suggest the claimed invention in which DNA, which is isolated using a silica based or silica coated porous matrix with specified pore sizes to directly bind genomic DNA in the absence of alcohol or chaotropic agents, is used as a template for real time PCR.

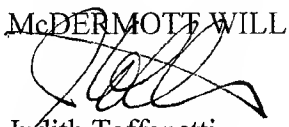
It is respectfully submitted that the rejection of claim 15 under 35 U.S.C. § 103(a) over Smith et al. in view of Heid et al. is respectfully traversed.

It is further submitted that the present application is in condition for allowance, an early notification thereof being earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Judith Toffenetti
Registration No. 39,048

600 13th Street, N.W.
Washington, DC 20005-3096
Phone: 202.756.8000 ASA::ajb
Facsimile: 202.756.8087
Date: November 16, 2010

Please recognize our Customer No. 20277 as our correspondence address.

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